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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,360

09/25/2003

James C. Powers

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08/23/2006

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EXAMINER

BRADLEY, CHRISTINA

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/671,360	Applicant(s) POWERS ET AL.	
	Examiner Christina Bradley	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 5-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 1-4, and the species Z-Leu-Abu-(CH₂)₃-4-morpholinyl (AK295), in the reply filed on 05/04/2006 is acknowledged. Claims 5-22 are withdrawn from consideration.

Claim Objections

2. Claims 1-4 are objected to because of the following informalities: in claim 1 on page 3, line 21, □-carbon should be α-carbon. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saatman *et al.* (*Proc. Natl. Acad. Sci. USA*, **1996**, *93*, 3428; citation 5 on the Information Disclosure Sheet of 10/20/2003) in view of Wang *et al.* (*J. Neuropathol. Exp. Neurol.*, **2000**, *59*, 599) and Schaecher *et al.* (*Neurochem. Res.*, **2001**, *26*, 731). Saatman *et al.* teach the administration of Z-Leu-Abu-(CH₂)₃-4-morpholinyl (AK295) to rats with experimental brain injury and memory and

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neuromotor dysfunction (see abstract). Saatman *et al.* do not teach that the AK295 treats axonal degeneration of the peripheral nervous system. Wang *et al.* teach that treatment with AK295 was equally protective in two *in vitro* models of axonal degeneration, a pathological feature of peripheral neuropathies (see abstract).

5. It would have been obvious to one of ordinary skill in the art to administer AK295 to patients suffering from axonal degeneration of the peripheral nervous system including those with degeneration attributable to multiple sclerosis or hereditary neuropathies. The skilled artisan would have been motivated to do so given the suggestion by Wang *et al.* that calpain inhibition may provide a strategy for preventing axonal degeneration and preserving neurologic function in a variety of peripheral and central nervous system disorders including hereditary neuropathies and multiple sclerosis (see page 605).

6. Furthermore, with regards to claim 2 and multiple sclerosis, Schaecher *et al.* teach that calpain plays a role in the pathophysiology of experimental allergic encephalomyelitis (EAE), an animal model of multiple sclerosis (see abstract). In EAE, calpain degrades myelin proteins. Expression of calpain and increased calpain activity is concomitant with loss of axon and myelin proteins in glial and inflammatory cells. Schaecher *et al.* suggest that calpain inhibitors may be used “as agents for the treatment of EAE” (see page 735).

7. There would have been a reasonable expectation of success given that AK295 is effective in *in vitro* models of peripheral axonal degradation (Wang *et al.*), is effective *in vivo* for treating related conditions (Saatman *et al.*), and inhibits an enzyme that plays “critical role” in demyelinating diseases according to Schaecher *et al.* Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

8. No claims are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.
10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cmb


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